(12) UK Patent Application (19) GB (11) 2 000 555 A

(21) Application No 7826209
(22) Date of filing 1 Jun 1978
(23) Claims filed 1 Jun 1978
(30) Priority data
(31) 27618/77
(32) 1 Jul 1977
(33) United Kingdom (GB)
(43) Application published 10 Jan 1979
(51) INT CL²
B65D 83/14
(52) Domestic classification
F1R 3A3D2 3A3D9
(56) Documents cited
GB 1109218
GB 1006751
(58) Field of search
F1R
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(54) **Aerosol dispensing device**

(57) A one-piece or two-piece oral applicator for use together with a pressurised aerosol medicament container,the applicator comprising (a) a disengageable means for fitting together the container and the applicator, (b) a hollow body extending longitudinally in the direction of the spray from the container valve together, (c) the hollow body comprising an end wall or baffle plate essentially at right angles to the direction of the spray and positioned 8.5 to 12.5 centimetres from the valve, (d) the hollow body having an internal cross-sectional area at right angles to the direction of the spray of not less than approximately 7 square centimetres, which area in either essentially constant or increases with increasing distance from said disengageable means, and optionally a relatively short neck portion adjacent to the container valve when the container and applicator are fitted together, and (e) the hollow body having an outlet forming leading to a mouthpiece.

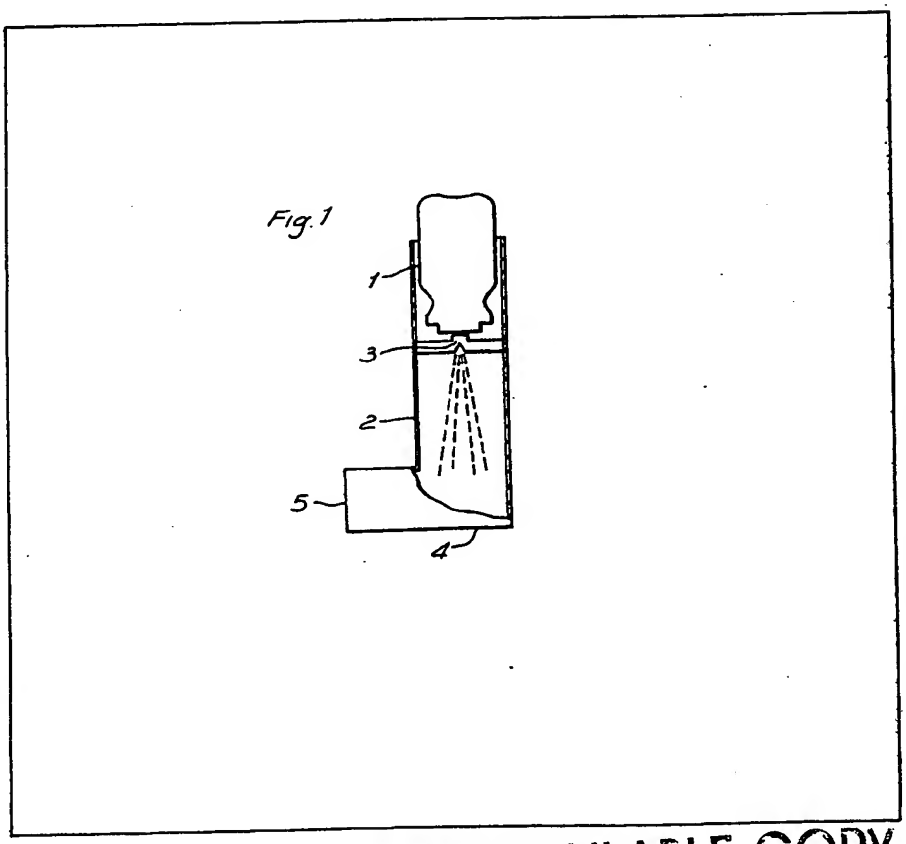


Fig. 1

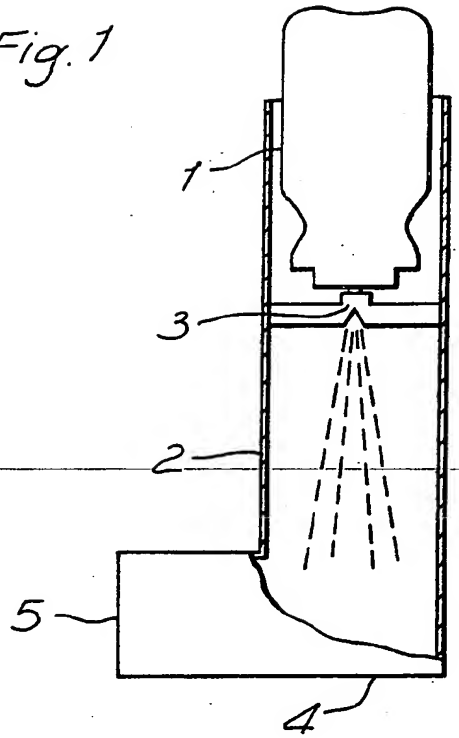


Fig. 2

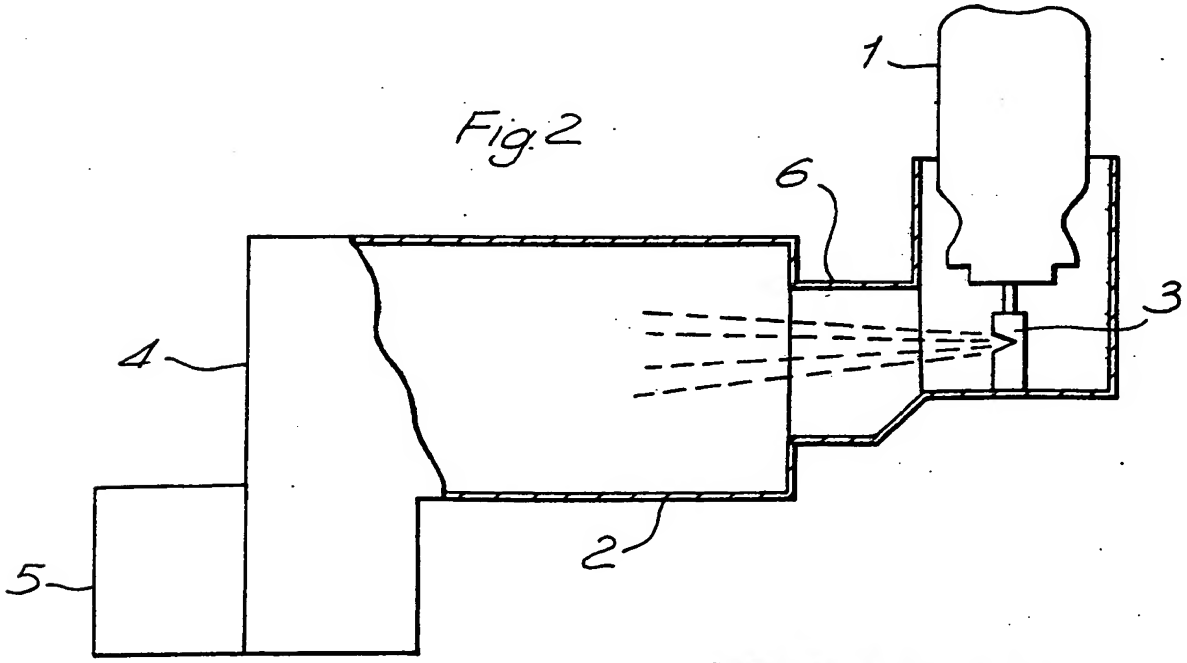


Fig.3

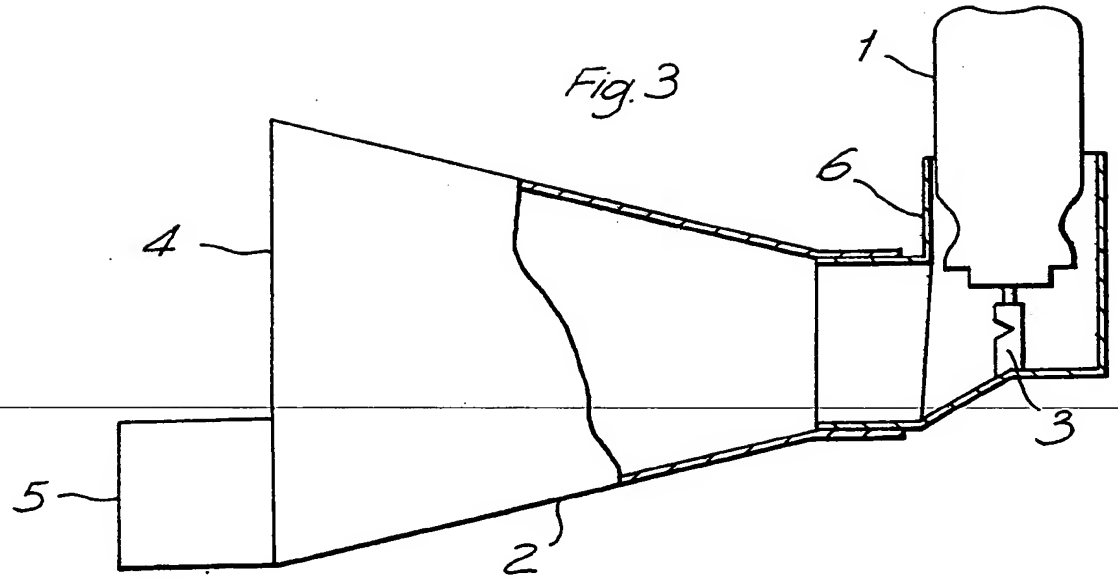


Fig.4

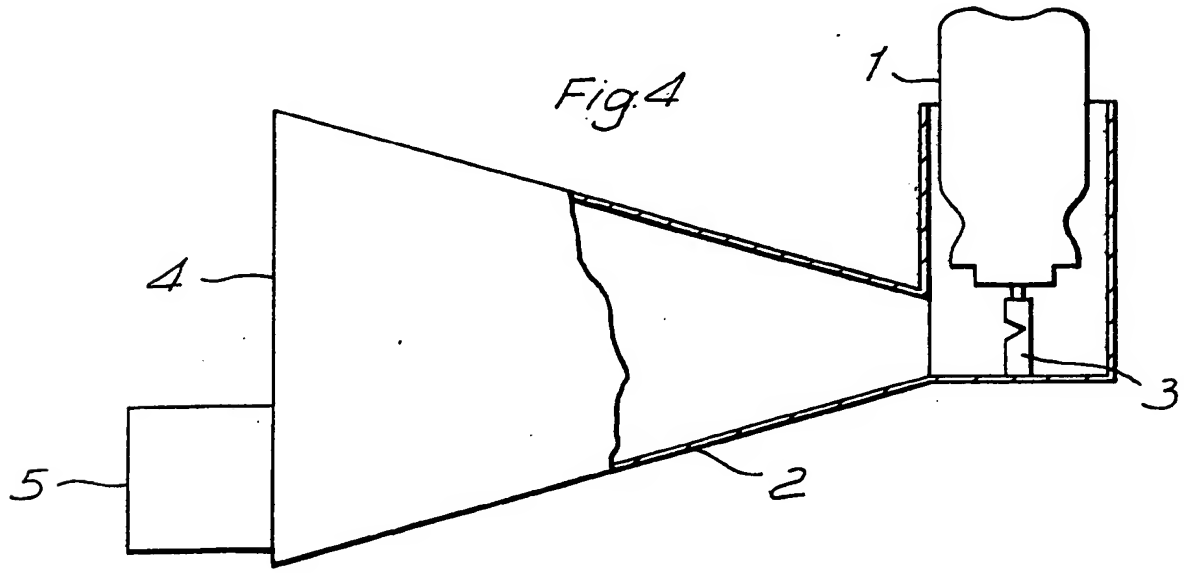


Fig 5

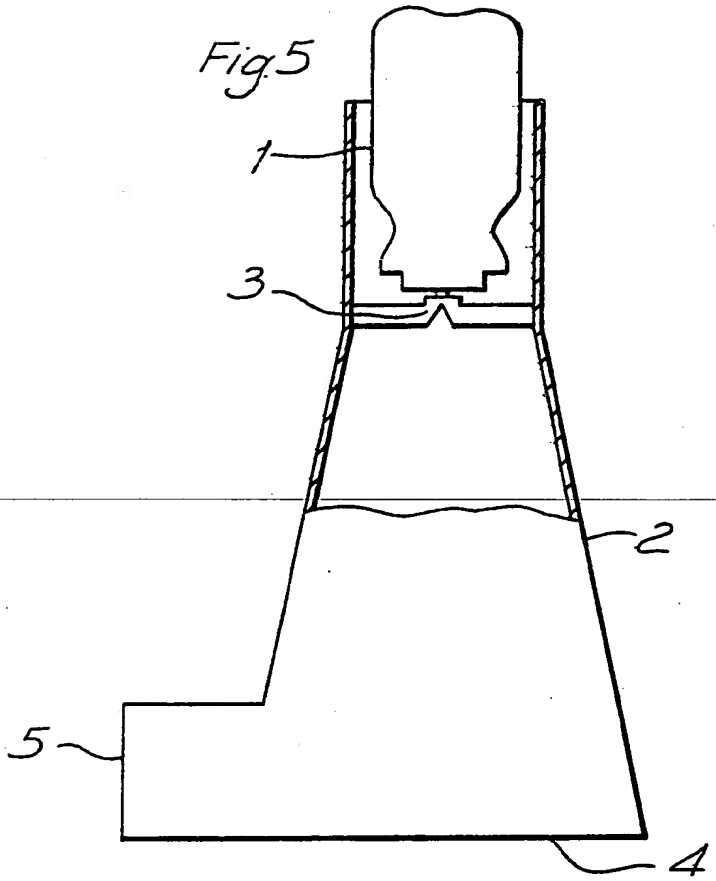


Fig 6

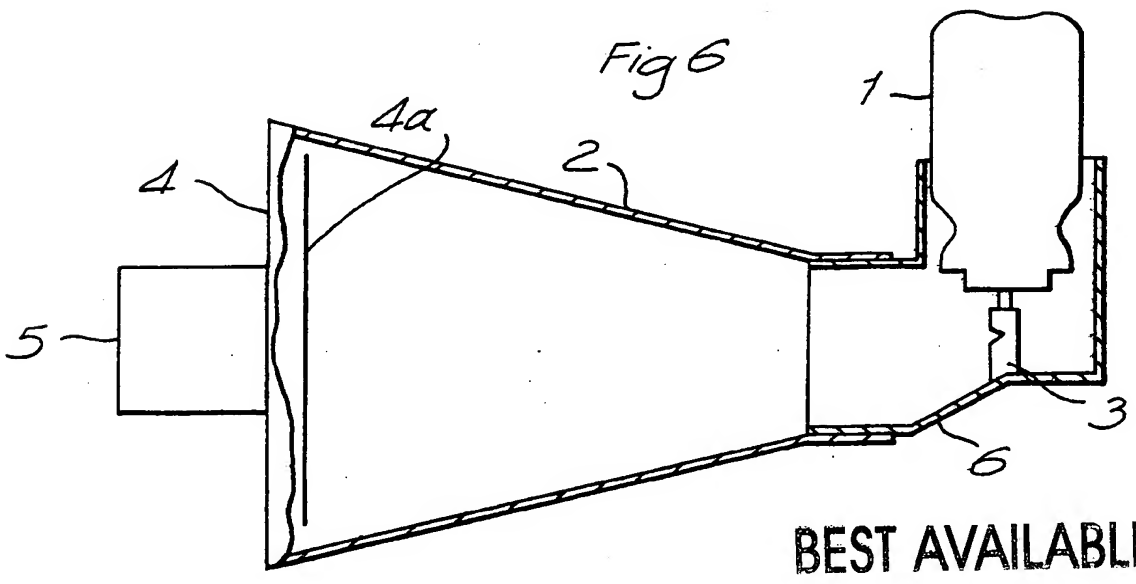
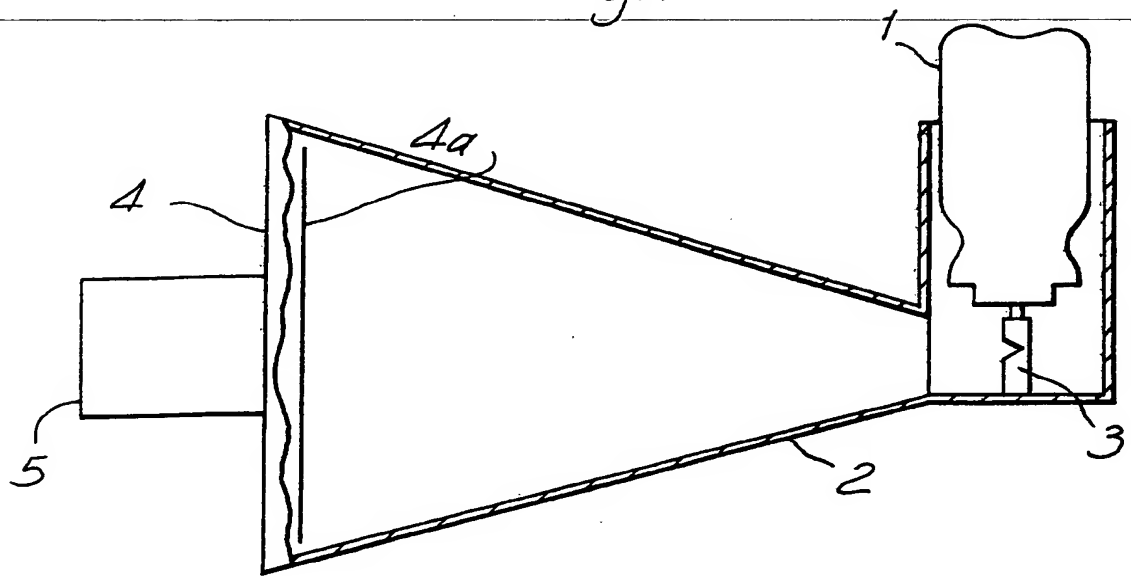


Fig. 7



SPECIFICATION

Aerosol dispensing device

This invention relates to an aerosol dispensing device which is adapted for the administration of a medicament-containing aerosol to the oral cavity of a user for the purpose of inhalation therapy.

Aerosol devices containing various medicaments are widely used for the relief and/or treatment of various disorders, for example asthma, hay fever and the like. Generally speaking, such a device comprises a canister containing a pressurised medicament-containing composition and fitted with a valve, usually a metered dispensing valve, and an oral applicator, the discharge end of which is shaped to conform to the mouth of the user. The device may be manually actuated, or it may be breath-actuated, that is, it may include a mechanism whereby the releast of a measured dose is triggered off by the user starting to inhale.

A great variety of aerosol devices of the type outlined above has been proposed and described in the patent and non-patent literature, and a considerable variety of such devices has been sold and used. One disadvantage of most known aerosol devices, and this applies to breath-actuated devices and to non-breath-actuated devices, is that approximately 50-60% of each particular dose does not reach the organ where it will exert the desired effect, that is, the lungs, because it is deposited in the mouth and pharynx. Thus, approximately one half of each dose does not reach the target organ. Also, the deposition and adsorption of the medicament in the mouth of pharynx can lead to certain cases to unwanted side-effects. It is an object of this invention to provide an oral applicator for an aerosol device which prevents most of this unwanted deposition in the user's mouth and pharynx. According to this invention, most of the material that would normally be deposited in the mouth and pharynx of the user is in effect trapped inside the applicator of this invention. The overall effect according to this invention is that most of the medicament-containing aerosol which leaves the applicator and enters the user's mouth reaches the lungs, giving valuable consistency in use. Also, there is only an insignificant amount of deposition of the medicament in the mouth and pharynx of the user, and therefore there is much less chance of unwanted side-effects.

According to the present invention there is provided an oral applicator adapted for use together with a pressurised aerosol medicament container, the said applicator comprising:

(a) a disengageable means for fitting together the container and the applicator,

(b) a hollow body extending longitudinally in the direction of the spray from the container valve when the container and applicator are fitted together and the container value is actuated,

(c) the said hollow body comprising an end wall or internal baffle plate essentially at right angles to the said direction of spray and positioned 8.5 to 12.5 centimetres from the valve when the container and applicator are fitted together,

(d) the said hollow body having an internal cross-sectional area at right angles to the said direction of spray of not less than approximately 7 square centimetres, and the said cross-sectional area being essentially constant or increasing with increasing distance from the said disengageable means, and

(e) the said hollow body having an outlet leading to a mouthpiece.

The applicator of this invention may be a one-piece device or it may be a two-piece device. In the latter case (which is illustrated in Figures 3 and 6) the applicator comprises:

(i) A relatively small connector which comprises a disengageable means for fitting together the container and the connector, and a disengageable means for fitting together the main applicator body and the connector, and

(ii) a main applicator body having the characteristic features described above in (a) to (e).

The said connector may, for example, be a conventional oral adaptor. Suitable disengageable fitting means are well known in the art, and any such means may be used in accordance with this invention.

The most important feature of this invention is the end wall or internal baffle plate which provides a partial barrier to the spray from the container nozzle, causing most of the spray to change direction at least once by approximately 90°. The end wall or baffle plate is positioned 8.5 to 12.5 cm., and preferably 9.5 to 10.5 cm., from the container valve. The baffle plate may be unbroken (that is, without holes) or it may contain a plurality of relatively small holes. It is to be understood that the end wall or baffle plate need not be flat. Thus, for example, the end wall may form part of a curved bend.

The main body part of the applicator may be of any suitable cross-section, for example circular or oval cross-section, and it may be tubular, i.e. of essentially constant cross-section, or it may be conical. In the latter case, the narrow end of the body is diposed towards the disengageable fitting means. The internal cross-sectional area of the main body part of the applicator, at right angles to the direction of the spray, should not be less than approximately 7 square centimetres at any point, provided that, as an optional feature, the applicator may include a relatively short neck portion adjacent to the container valve when the container and applicator are fitted together. The said neck portion should not be more than approximately 2 cm. in length in the longitudinal direction. In the case of a one-piece device of this invention, the said neck portion should have an internal cross-sectional area of not less than approximately 0.75 square centimetres (where the neck portion is circular, it may have a diameter of 0.5-2.5cm., and preferably 1 cm.). In the case of a two-piece device of this invention, the said neck portion should have an internal cross-sectional area of not less than approximately 6 square centimetres.

The applicator of this invention may be fabricated

by conventional methods from any suitable material, for example a plastics material.

According to a further feature of the invention there is provided the combination of a pressurised aerosol medicament container and an applicator as defined above.

In order that the invention may be more clearly understood, several embodiments will now be described, by way of example only, with reference to the accompanying drawings which are all axial sections (in part), and in which the aerosol containers are of the type which are used in the inverted position.

In Figure 1 the aerosol container 1 is disengageably fitted to the applicator, which includes a tubular portion 2 of circular cross-section (diameter 3.5cm.) extending longitudinally in the direction of the spray from the metered dose valve 3. The applicator has anend wall (8.5cm. from the valve 3) and a mouthpiece 5.

In Figure 2 the spray from the metered dose valve 3 is at right angles to the longitudinal line of the body of the container 1. The tubular portion 2 (diameter 3.5cm.) is integral with a short neck portion 6. The distance from the valve 3 to the end of the neck portion 6 is 2.5cm. The applicator has an end wall 4 (9.5cm. from the valve 3) and a mouthpiece 5.

In Figure 3 the aerosol container 1 is fitted to a conventional oral adaptor 6. The adaptor 6 is slidably fitted to the main body of the applicator, which has a conical portion 2, an end wall 4, and a mouthpiece 5. The end wall 4 (diameter 6cm.) is 8.15-12.5cm., and preferably 9.5cm., from the valve 3.

Figure4 is similar to Figure 3, except that it illustrates a one-piece device. Figure 5 illustrates a similar device to Figure 1, except that the applicator has a conical body.

In Figure 6 the aerosol container 1 is fitted to a conventional oral adaptor 6. The adaptor 6 is slidably fitted to the applicator which has a conical body 2. The applicator has an internal baffle plate 4a and a centrally positioned mouthpiece 5. The baffle plate 4a (diameter 2- 5.8cm.) is positioned 8.5 - 12.4cm., and preferably 9.5cm., from the metered dose valve 3. The gap between the edge of the baffle plate and the side wall of the conical body is 0.06 - 2cm. The end wall 4 (diameter 6cm.) is 8.6 - 12.5cm., and preferably 10cm., from the metered dose valve.

Figure 7 illustrates a one-piece conical device which is broadly similar to that illustrated in Figure 4, but which contains an internal baffle plate 4a and a centrally-positioned mouthpiece 5. The baffle plate (diameter 2- 5.8cm.) is positioned 8.5 - 12.4cm., and preferably 9.6cm., from the metered dose valve 3. The gap between the edge of the baffle plate and the side wall of the conical body is 0.05 - 2cm. The end wall 4 (diameter 6cm.) is 8.6 - 12.5 cm., and preferably 10cm., from the metered dose valve.

In using the devices illustrated in Figures 1 to 7, the patient puts the mouthpiece 5 into his mouth and manually discharges a dose from the container 1 by pressing the container relative to the adaptor 2, at the same time inhaling the discharged material.

CLAIMS:-

1. An oral applicator adapted for use together with a pressurised aerosol medicament container, the said applicator comprising:

(a) a disengageable means for fitting together the container and the applicator,

(b) a hollow body extending longitudinally in the direction of the spray from the container valve when the container and applicator are fitted together and the container valve is actuated,

(c) the said hollow body comprising an end wall or internal baffle plate essentially at right angles to the said direction of spray and positioned 8.5 to 12.5 centimetres from the valve when the container and applicator are fitted together,

(d) the said hollow body having an internal cross-sectional area at right angles to the said direction of spray of not less than approximately 7 square centimetres, and the said cross-sectional area being essentially constant or increasing with increasing distance from the said disengageable means, and

(e) the said hollow body having an outlet leading to a mouthpiece.

2. A two-piece applicator as claimed in claim 1 comprising:

(i) a relatively small connector which comprises a disengageable means for fitting together the container and the connector, and a disengageable means for fitting together the main applicator body and the connector, and

(ii) a main applicator body having the characteristic features claimed in claim 1(a) to 1(e).

3. An applicator as claimed in claim 1 for 2 in which the end wall or internal baffle plate is positioned 9.5 to 10.5cm. from the container valve.

4. An applicator as claimed in any one of claims 1 to 3 in which the baffle plate is unbroken.

5. An applicator as claimed in any one of claims 1 to 3 in which the baffle plate contains a plurality of relatively small holes,

6. An applicator as claimed in any one of claims 1 to 5, which includes a relatively short neck portion, not more than approximately 2cm. in length in the longitudinal direction, and adjacent to the container valve when the container and applicator are fitted together.

7. A combination of a pressurised aerosol medicament container and an applicator as claimed in any one of claims 1 to 6.

8. An oral applicator, claimed in claim 1, substantially as described in any one of the drawings.

9. A combination of an aerosol medicament container and an applicator, substantially as described in any one of the drawings.

Printed for Her Majesty's Stationery Office, by Croydon Printing Company Limited, Croydon Surrey, 1978.
Published by the Patent Office, 25 Southampton Buildings, London, WC2A 1AY, from which copies may be obtained.